

PECFAVED
JAN 2 9 2000

0961 '01 MAR -8 A11:44

January 23, 2001

Express Mail Label No. EE877603171US

74218

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. S.W. Washington, D.C. 20204

RE: Notification of marketing a dietary supplement that bears on its label or its labeling a statement provided for in section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

Dear FDA Consumer Safety Officer:

USANA Health Sciences, Inc. submits this notification for its dietary supplement products that bear statements of nutritional support in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

Manufacturer of Dietary Supplement:

USANA Health Sciences, Inc.

3838 West Parkway Blvd.

Salt Lake City, Utah 84120-6336

Name of Dietary Supplements:

(including brand name)

"Beautinutrients", "L•E•A•N Diet Bar"

## Text of Statements Being Made for "Beautinutrients":

"Inner nutrients support outer beauty with borage oil, fax oil, antioxidant-rich green tea and grape seed extracts, as well as vitamins, phytonutrients, and amino acids."

"The skin receives essential nutrients from within to support optimal skin structure and function."

"Delivering maximum benefits to the skin from the inside out, this synergistic formula combines skin-essential antioxidants, vitamins, phytonutrients and amino acids that are designed to nourish the skin from within and support optimal skin structure and function."

975 0162

DET 68 46

"Beautinutrients contain vital elements that work synergistically to support beautiful skin from within."

"Green tea and grape seed contain proanthocyanidins, which are known to help neutralize free radicals."

"Our diet often lacks Omega 3 and Omega 6 essential fatty acids which are vital for overall health and well-being. Sensé obtains these key ingredients from organic coldpressed borage oil and organic high-lignin flaxseed oil."

## Text of Statements Being Made for "L•E•A•N Diet Bar":

"USANA's team of scientists developed this exclusive formula that increases weight loss, causes a decrease in appetite, and curbs carbohydrate cravings."

"5-HTP has been shown in controlled studies to increase weight loss, cause a decrease in appetite, and increase feelings of fullness."

"Green tea has been studied for its thermogenic properties and fat oxidation."

"Fiber has been shown to elicit a sense of fullness, which makes people eat fewer calories."

## John B. McCandless declares:

- 1. That he is Senior Vice President and Chief Operating Officer of Usana Health Sciences, Inc. (hereinafter "applicant") and is authorized to make this declaration;
- 2. That information contained in this statement is complete and accurate, and that USANA Health Sciences, Inc. has substantiation that the statement is truthful and not misleading.

DATED this 24 day of January 2001.

USANA Health Sciences, Inc.

By:

John B. McCandless
Senior Vice President and
Chief Operating Officer